Federal Register: November 13, 1998 (Volume 63, Number 219)]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Revisions to the Mandatory Guidelines.

SUMMARY: On September 30, 1997, the Department of Health and Human Services (HHS) published a notice in the Federal Register, 62 FR 51118, revising the testing cutoff levels for opiates that were in Mandatory Guidelines for Federal Workplace Drug Testing Programs, 59 FR 29916 (June 9, 1994). The Federal Register notice indicated that May 1, 1998, was the effective date for implementing the new opiate testing cutoff levels. Subsequent to the publication of that notice, it became clear that not all manufacturers of immunoassay test kits would be able to provide a sufficient supply of the modified opiate reagents by that date, that it would take more time for the certified drug testing laboratories to validate the new immunoassay test kits and confirmatory test procedures for opiates, and that it would take more time to verify the performance of each laboratory using external performance testing samples. For these reasons, on February 4, 1998, the Division of Workplace Programs sent a letter to all Federal agencies, HHS certified and applicant drug testing laboratories, and immunoassay test kit manufacturers informing them that the effective date would be delayed 4 to 6 months beyond the May 1, 1998, effective date published in the September 30, 1997, Federal Register notice. This notice establishes a new effective date.

EFFECTIVE DATE: December 1, 1998.

FOR FURTHER INFORMATION CONTACT:
Dr. Donna M. Bush, Drug Testing Team Leader, Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, tel. (301) 443-6014.

SUPPLEMENTARY INFORMATION: The Division of Workplace Programs is satisfied that the manufacturers of test kits can provide an adequate

supply of the modified opiate test kits to the certified laboratories by the December 1, 1998, effective date. During June 1998, the certified laboratories received a special set of performance testing samples from the National Laboratory Certification Program (NLCP) contractor to evaluate each laboratory's ability to conduct the initial and confirmatory tests at the revised testing levels for opiates. The results for this set of samples indicate that all the laboratories were able to conduct the initial test using the modified opiate test kits provided by the immunoassay test kit manufacturers. Based on this information, all the manufacturers were contacted and informed that a December 1, 1998, effective date has been selected. There was unanimous agreement among the manufacturers that each would be able to provide a sufficient number of kits to the laboratories before that date. A second set of special performance testing samples will be sent to the laboratories in September 1998 to further ensure that all laboratories are prepared to test specimens for opiates using the revised testing levels.

The September 30, 1997, Federal Register notice discusses the background and summary of public comments regarding the changes to the testing cutoff levels of opiates. The Department's responses to those comments and the proposed policy have not changed. However, to ensure that there is no misunderstanding, the changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916) are restated in this notice.

Information Collection Requirements: There are no new paperwork requirements subject to the Office of management and Budget approval under the Paperwork Reduction Act of 1980.

Dated: September 21, 1998.
Nelba Chavez,
Administrator, Substance Abuse and Mental Health Services Administration.

Dated: October 31, 1998.
Donna E. Shalala,
Secretary.

The following amendments are made to the Mandatory Guidelines for Federal Workplace Drug Testing Programs published on June 9, 1994 (59 FR 29916):

Subpart B

1. Section 2.4(e)(1), the initial test level for opiate metabolites appearing in the table, is amended by changing the value of ''300'' to

‘‘2,000’’ and deleting the footnote that had specified a 25 ng/mL testing level if the immunoassay test was specific for free morphine.

2. Section 2.4(f)(1), the confirmatory test level for morphine appearing in the table, is amended by changing the value of ‘‘300’’ to ‘‘2,000.’’

3. Section 2.4(f)(1), the confirmatory test level for codeine appearing in the table, is amended by changing the value of ‘‘300’’ to ‘‘2,000.’’

4. Section 2.4(f)(1), the table of confirmatory test levels, is amended by adding a new line under opiates to read as follows:

6-Acetylmorphine\4\ …….10 ng/mL

\4\ Test for 6-AM when the morphine concentration exceeds 2,000 ng/mL.

5. Section 2.4(f)(1), the table of confirmatory test levels, is amended by adding a new footnote under the table to read as follows:

[FR Doc. 98-30403 Filed 11-12-98; 8:45 am]
BILLING CODE 4160-20-M